UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

WEST VIRGINIA PIPE TRADES HEALTH & WELFARE FUND, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. MEDTRONIC, INC., WILLIAM A. HAWKINS, GARY L. ELLIS and RICHARD E. KUNTZ, Defendants.	Civ. No. CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

INTRODUCTION

1. This is a securities class action on behalf of all persons who purchased or otherwise acquired Medtronic, Inc. ("Medtronic" or the "Company") common stock between December 8, 2010 and August 3, 2011, inclusive (the "Class Period"), against Medtronic and certain of its current and/or former officers for violations of the Securities Exchange Act of 1934 ("1934 Act"). These claims are asserted against Medtronic and certain of its officers who made materially false and misleading statements during the Class Period in press releases, analyst conference calls and filings with the U.S. Securities and Exchange Commission ("SEC").

2. Medtronic is engaged in medical technology. Following its introduction in 2002, the Company's INFUSE® Bone Graft ("Infuse") product became an integral part of Medtronic's Spinal unit, which represented 21% of Medtronic's 2011 revenue, contributing tremendously to the division's growth. Medtronic's Infuse product has been approved by the Food and Drug Administration ("FDA") for use in some fusion surgeries in the lower back as well as for some oral and dental uses.

3. Throughout the Class Period, defendants violated the federal securities laws by disseminating false and misleading statements to the investing public regarding the use of the Infuse product for reduction of pain and complications associated with treating degenerative disc disease. Infuse contains a recombinant human bone morphogenetic protein, rhBMP-2, for spinal, trauma and oral maxillofacial applications. As a result of defendants' false statements, Medtronic's stock traded at artificially inflated prices during the Class Period, reaching a high of $43.20 per share on May 18, 2011.

4. On June 23, 2011, Medtronic issued a press release regarding the Infuse product, which stated in part:

> We are in receipt of an inquiry from Senators Grassley and Baucus requesting information related to our INFUSE® Bone Graft product and intend to respond. Additionally, it is important to emphasize that the three adverse events highlighted in the letter are already listed as warnings on our FDA approved product labeling for INFUSE® Bone Graft. Furthermore, patient safety is of the utmost important [sic] to Medtronic. Accordingly, we provide PMA clinical study adverse event data to the FDA irrespective of any financial relationship between the company and the clinical investigator or study author.

5. Later, on June 28, 2011, an entire issue of *The Spine Journal* was devoted to the Infuse product, including the conflicts of interest by researchers who had performed studies on Infuse and the underappreciated risks and side effects associated with Infuse. Five doctors wrote in a joint editorial that accompanied the reports: "It harms patients to have biased and corrupted research published." One article in *The Spine Journal* noted that the median amount of money going to researchers ranged from $12 to $16 million, with most going to a few individuals. Another article noted that information reported in medical journals following FDA approval played down Infuse's risks and slanted the articles in favor of the use of Infuse over bone grafts. *The Spine Journal* authors noted that the incidence of adverse events experienced in connection with Infuse's use ranged from 10% to 50% and included male sterility, infection, bone loss and unwanted bone growth.

6. In response to the articles in *The Spine Journal*, Medtronic issued a press release that stated in part:

> Following is a statement from Omar Ishrak, chairman and chief executive officer of Medtronic, Inc. on a series of articles on recombinant human Bone Morphogenetic Protein-2 (rhBMP-2) published in a recent edition of *Spine Journal*.

> "Integrity and patient safety are my highest priorities. While the *Spine Journal* articles raise questions about researchers' conclusions in their published peer-reviewed literature, the articles do not raise questions about the data Medtronic submitted to the FDA in the approval process or the information available to physicians today through the instructions for use brochure attached to each product sold.
>
> "Based on that data, we strongly believe that the safety profile reported to the FDA and summarized in the product label support the safe use of rhBMP-2 for the identified indications. We remain committed to ongoing study of the safety and efficacy of rhBMP-2, especially in applications not covered by FDA labeling.

7. Also on June 28, 2011, Medtronic filed its Form 10-K with the SEC for the period ended April 29, 2011. The Form 10-K stated in part:

> Looking ahead, we expect our Restorative Therapies Group should be impacted by the following:
>
> * * *
>
> - Any effects on our business from discussions in the medical literature, or inquiries from governmental authorities, relating to our INFUSE Bone Graft product. In June 2011, articles in a medical journal suggested that some physicians' peer-reviewed studies may have underreported complications and adverse events associated with INFUSE. These articles did not question the integrity of the data provided by Medtronic to the FDA for product approval or the disclosure of safety issues on the product's Instructions for Use for approved indications.

8. On this news, Medtronic's stock dropped $0.92 per share to close at $38.09 per share on June 29, 2011, a one-day decline of nearly 3% on volume of 10 million shares.

9. Once analysts had a chance to absorb the disclosures in *The Spine Journal*, they downgraded Medtronic's stock, causing further declines in Medtronic's stock price. Analysts stated the following:

- July 5, 2011 – Wells Fargo Securities:

Summary: We believe the InFuse papers published in The Spine Journal on June 28 will have broader implications for MDT [Medtronic] and its spine business than the Street currently expects. We think The Spine Journal papers could lead to the following outcomes: (1) a significant reduction in the sales of MDT's spine biologics franchise; (2) a reduction in the sales of MDT's spinal instrumentation business; (3) a potential FDA review of InFuse, including an Advisory Committee meeting, which could lead to more limited use of InFuse; (4) potentially larger criminal penalties in the Department of Justice (DOJ) investigation of the off-label promotion of InFuse; (5) the potential emergence of class action lawsuits; and (6) the potential sale of the entire spine business. While we previously expected MDT's spine biologics franchise to decline by 9% in FY2012 due to the non-approvable letter for Amplify (higher dose version of InFuse) and a likely DOJ settlement for off-label promotion of InFuse in CY2011, the attack of [sic] InFuse by The Spine Journal and the accompanying negative media coverage was unexpected. Given the increasing negative publicity for InFuse and the likely negative spillover to MDT's larger spinal instrumentation business, we are reducing our FY2012E-13E sales by $209MM and $322MM, respectively, to $16.491B and $17.045B. In addition, we are lowering our FY2012E-13E EPS by $0.04 and $0.01, respectively, to $3.43 and $3.74. Our new FY2012E EPS is at the low end of MDT's FY2012 guidance range. We are lowering our valuation range to $36-37 from $46-47 which assumes 10x our new CY2012 EPS estimate.

- July 5, 2011 – J.P. Morgan:

  Surgeons closest to the issue, or at least those that have given it the greatest attention, are having an even stronger reaction. Of the 48 surgeons we surveyed, 63% expect to reduce their Infuse usage in the coming year. But that figure jumps to 90% when we sample those surgeons that have actually read the *TSJ* articles; among this group the decline is 54% – double the overall rate. The [sic] suggests the hit to utilization could increase as physicians take the time to read the details of the articles. An FDA panel to discuss the data, which we view as likely, could also lead to yet another round of negative press for Infuse and further elevate the profile of the concerns raised by the *TSJ* authors.

10. Following these reports, Medtronic's stock price dropped to below $38 per share.

11. Finally, on August 3, 2011, Medtronic announced it would publicly release Infuse data for Yale University ("Yale") researchers to conduct a review. Medtronic agreed to pay Yale $2.5 million to assemble a steering committee, hire two research organizations to review studies of the Infuse product and design a database that could be used by outsiders to get access to the information. Harlan Krumholz, professor of internal medicine, epidemiology and public health at Yale, who was to lead the work, noted: "'It's a historic agreement and one I hope will set a standard for everyone else in the industry. For too long we've been in a situation where questions are raised about the safety of a product but companies don't share the information.'"

12. *Bloomberg News* noted that:

> While it is a good first step, questions will remain after the analysis is done, [Eugene Carragee, chief of spinal surgery at Stanford School of Medicine] said. Infuse is predominantly used in surgeries that haven't been studied by Medtronic, Carragee said. Thus, the two reviews and the database won't provide any clear answers for those patients, he said.
>
> "They simply are not going to have enough data on the main usage of it to give a really precise estimate of how safe or dangerous it is," said Carragee, who is editor in chief of the Spine Journal and led the publication's review of Infuse.
>
> The main problem with the published Infuse trial results is that they didn't include the product's complications, Carragee said. Surgeons didn't know to look for things like cancer and male sterility, he said. That will reduce the number of cases reported to the company and U.S. Food and Drug Administration, and they won't show up in the analysis, he said.
>
> Diminished Accuracy
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> "The accuracy of that has been severely impacted by 10 years of telling everybody that there are no problems," he said. "I never reported a male

> sterility event to the company or the FDA because I didn't think it was a complication of the product. It's the same thing for infections or cancer or bladder problems. It was all news to us."

13. On this news, Medtronic's stock price dropped $1.47 per share to close at $32.84 per share on August 4, 2011, a one-day decline of 4% on volume of 11.5 million shares.

14. The true facts, which were known by defendants but concealed from the investing public during the Class Period, were as follows:

(a) The Company had engaged in a scheme with certain researchers to downplay the risks and side effects associated with Infuse.

(b) The Company failed to disclose that once the risks associated with the Infuse product were fully appreciated by surgeons, use of the product would drop significantly.

15. As a result of defendants' false statements, Medtronic stock traded at artificially inflated levels during the Class Period. However, after the above revelations seeped into the market, the Company's shares were hammered by massive sales, sending them down nearly 24% from their Class Period high.

JURISDICTION AND VENUE

16. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the 1934 Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 (17 C.F.R. §240.10b-5) promulgated thereunder by the SEC.

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the 1934 Act (15 U.S.C. §78aa).

18. Venue is proper in this District pursuant to §27 of the 1934 Act and 28 U.S.C. §1391(b), as many of the acts and practices complained of herein occurred in substantial part in this District. Medtronic maintains its principal place of business in this District, and certain of the acts and conduct complained of herein, including dissemination of materially false and misleading information to the investing public, occurred in this District.

19. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

PARTIES

20. Plaintiff West Virginia Pipe Trades Health & Welfare Fund purchased the common stock of Medtronic during the Class Period as set forth in the certification attached hereto and was damaged as the result of defendants' wrongdoing as alleged in this complaint.

21. Defendant Medtronic develops, manufactures, and markets medical devices worldwide. Medtronic maintains its headquarters at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

22. Defendant William A. Hawkins ("Hawkins") was, at relevant times, the Company's Chief Executive Officer ("CEO") and Chairman of the Board until he retired from the Company in June 2011. Defendant Hawkins was compensated more than $9 million per year for fiscal 2010 and fiscal 2011. [1]

[1] Medtronic's fiscal year ends the last Friday in April.

23. Defendant Gary L. Ellis ("Ellis") is, and at all relevant times was, the Company's Chief Financial Officer ("CFO") and Senior Vice President. Defendant Ellis was compensated more than $3 million in each of fiscal 2010 and 2011.

24. Defendant Richard E. Kuntz ("Kuntz") is, and at all relevant times was, the Company's Senior Vice President and Chief Scientific Officer.

25. The defendants named above in ¶¶22-24 are referred to herein as the "Individual Defendants."

26. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Medtronic's quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. They were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions with the Company, and their access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements pleaded herein.

FRAUDULENT SCHEME AND COURSE OF BUSINESS

27. Defendants are liable for: (i) making false statements; or (ii) failing to disclose adverse facts known to them about Medtronic. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Medtronic common stock was a

success, as it: (i) deceived the investing public regarding Medtronic's products, prospects and business; (ii) artificially inflated the price of Medtronic common stock; and (iii) caused plaintiff and other members of the Class to purchase Medtronic common stock at inflated prices.

BACKGROUND

28. Medtronic develops, manufactures, and markets medical devices worldwide. The Company's Cardiac Rhythm Disease Management segment primarily offers pacemakers, implantable defibrillators, leads, ablation products, electrophysiology catheters, insertable cardiac monitors, and information systems for cardiac rhythm disease management. Its Spinal segment provides thoracolumbar, cervical, and interbody spinal devices, bone growth substitutes, and devices for vertebral compression fractures and spinal stenosis. The CardioVascular segment offers coronary and peripheral stents and related delivery systems, endovascular stent graft systems, heart valve replacement technologies and tissue ablation systems, and open heart and coronary bypass grafting surgical products. The Neuromodulation segment provides therapeutic and diagnostic devices, including implantable neurostimulation systems, implantable drug delivery devices, and urology and gastroenterology products. The Diabetes segment offers external insulin pumps and related consumables, continuous glucose monitoring systems, and subcutaneous glucose sensors. The Surgical Technologies segment provides products to treat conditions of the ear, nose, and throat, as well as certain neurological disorders, and offers powered tissue-removal systems and other microendoscopy instruments, implantable devices, nerve monitoring systems, disposable fluid-control products, hydrocephalus shunt devices, external drainage

systems, cranial fixation devices, neuroendoscopes, dura repair products, image-guided surgery systems, and a disease therapy device. The Physio-Control segment offers external defibrillators, including manual defibrillator/monitors used by hospitals and emergency response personnel, and automated external defibrillators used in commercial and public settings and related data management solutions and support services.

29. On September 15, 2008, Medtronic's stock closed at $53.23 per share. Thereafter, as media scrutiny grew concerning allegations that Medtronic promoted off-label uses of its Infuse product and engaged in inappropriate dealings with doctors, Medtronic's stock began to slide. By the end of September 2008, Medtronic's stock closed at $50.10 per share.

30. On November 18, 2008, Medtronic revealed that the Department of Justice had initiated an investigation related to unapproved uses of Medtronic's Infuse product. By 2010, Medtronic's stock had stabilized. However, there remained undisclosed risks and adverse reactions to Infuse which defendants concealed, including the financial arrangements they had made with researchers.

DEFENDANTS' FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

31. On December 8, 2010, Medtronic filed its Form 10-Q with the SEC for the period ended October 29, 2010. The Form 10-Q represented that:

> We work to improve patient access through ***well-planned studies which show the safety, efficacy, and cost effectiveness of our therapies***, and our alliances with patients, clinicians, regulators, and reimbursement agencies. Our investments in research and development, strategic acquisitions, expanded clinical trials, and infrastructure provide the foundation for our growth. We are confident in our ability to drive long-term shareholder value using

> principles of our Mission, our strong product pipelines, and continued commitment to innovative research and development.
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> * * *
>
> Spinal net sales for the three and six months ended October 29, 2010 were $850 million and $1.680 billion, a decrease of 1 percent and 5 percent, respectively, over the same periods in the prior fiscal year. The decrease in Spinal net sales for both the three and six months ended October 29, 2010 was primarily due to a continued decrease in demand for the Kyphon Balloon Kyphoplasty (BKP) driven in part by the August 2009 vertebroplasty articles in the *New England Journal of Medicine*. We have also seen a decrease in the number of Spinal procedures as certain patients are postponing elective procedures due to the current macroeconomic conditions. In addition, Spinal net sales were negatively impacted by continued pricing pressures and a challenging reimbursement environment in many of our major markets

32. On February 22, 2011, Medtronic issued a press release announcing its fiscal third quarter 2011 financial results. The Company reported earnings of $922 million, or $0.86 diluted earnings per share ("EPS"), and revenue of $3.961 billion for the quarter ended January 28, 2011.

33. After releasing its fiscal third quarter 2011 results on February 22, 2011, Medtronic hosted a conference call for analysts, media representatives and investors during which defendant Hawkins represented the following:

> [HAWKINS:] So first on the AMPLIFY. Again, this is more of clarification, ***this is not INFUSE***. I mean, this is kind of a new indication and it is a new kind of formulation. But we're continuing to work with the FDA to figure out kind of where they are on this. We were encouraged by the panel vote, which was in support of the approval. And so as we learn more, we'll let you know. But it's incremental to kind of our current business. And so if there was a reason for the FDA to delay this anymore***, it's not going to have a significant impact. It won't have any really impact on our current business***. It's really all upside for us.
>
> [ANALYST:] Just to clarify that, Bill. You don't feel that not having like posterior lumbar fusion is probably the biggest off-label to use of INFUSE and you don't think not getting AMPLIFY approved could result in retrenchment there?

> [HAWKINS:] No. We've been very clear with our people in terms of the appropriate indications for INFUSE and so I don't see anything that would change as the result of AMPLIFY not getting approved. So again, ***there's a different formulation***. It's really a different product than INFUSE.

34. On March 9, 2011, Medtronic filed its Form 10-Q with the SEC for the period ended January 28, 2011, which included the same results previously reported in its February 22, 2011 press release. The Form 10-Q represented that:

> We remain committed to our Mission of developing lifesaving and life-enhancing therapies to alleviate pain, restore health, and extend life. The diversity and depth of our current product offerings enable us to provide medical therapies to patients worldwide. We work to improve patient access through well-planned studies which show the safety, efficacy, and cost-effectiveness of our therapies, and our alliances with patients, clinicians, regulators, and reimbursement agencies. Our investments in research and development, strategic acquisitions, expanded clinical trials, and infrastructure provide the foundation for our growth. We are confident in our ability to drive long-term shareholder value using principles of our Mission, our strong product pipelines, and our continued commitment to innovative research and development.

35. On May 18, 2011, Medtronic stock reached its Class Period high of $43.20 per share.

36. On May 24, 2011, Medtronic issued a press release announcing its fiscal fourth quarter and year-end 2011 financial results. The Company reported earnings of $776 million, or $0.72 diluted EPS, and revenue of $4.295 billion for the fourth quarter ended April 29, 2011. Additionally, the Company reported earnings of $3.096 billion, or $2.86 diluted EPS, and revenue of $15.933 billion for fiscal year 2011.

37. After releasing its fiscal fourth quarter and year-end 2011 results on May 24, 2011, Medtronic hosted a conference call for analysts, media representatives and investors during which defendant Ellis represented the following:

> In the U.S., we resolved all 3 warning letters and we continue to focus on meaningful quality improvement. ***Medtronic continues to set the standard for quality in the industry***.
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> We also launched a number of innovative new products in FY '11, including the Protecta ICD, Revo MRI pacemaker, and Arctic Front cryoballoon in our CRDM business. In CardioVascular, we launched and gained share with the Resolute Integrity drug-eluting stent in Europe, as well as the Integrity bare-metal stent and Endurant AAA stent graft in the U.S.
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> * * *
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> Biologics revenue of $227 million grew 4%. Results were driven by our recent acquisition of Osteotech. Sales of INFUSE declined in the quarter due to softer procedural volumes and contingent mix pressure from the shift to smaller kits. Although we received a non-approvable letter on AMPLIFY, we continued to work with the FDA to determine the path to approval and remain optimistic that we can bring this product to market.

38. On June 23, 2011, Medtronic issued a press release regarding the Infuse product, which stated in part:

> We are in receipt of an inquiry from Senators Grassley and Baucus requesting information related to our INFUSE® Bone Graft product and intend to respond. Additionally, it is important to emphasize that the three adverse events highlighted in the letter are already listed as warnings on our FDA approved product labeling for INFUSE® Bone Graft. Furthermore, patient safety is of the utmost important [sic] to Medtronic. Accordingly, we provide PMA clinical study adverse event data to the FDA irrespective of any financial relationship between the company and the clinical investigator or study author.

39. Later, on June 28, 2011, an entire issue of *The Spine Journal* was devoted the Infuse product, including the conflicts of interest by researchers who had performed studies on Infuse and the underappreciated risks and side effects associated with Infuse. Five doctors wrote in a joint editorial that accompanied the reports: "It harms patients to have biased and corrupted research published." One article in *The Spine Journal* noted that the median amount of money going to researchers ranged from $12 to $16 million, with most

going to a few individuals. Another article noted that information reported in medical journals following FDA approval played down Infuse's risks and slanted the articles in favor of the use of Infuse over bone grafts. *The Spine Journal* authors noted that the incidence of adverse events experienced in connection with Infuse's use ranged from 10% to 50% and included male sterility, infection, bone loss and unwanted bone growth.

40. In response to the articles in *The Spine Journal*, Medtronic issued a press release that stated in part:

> Following is a statement from Omar Ishrak, chairman and chief executive officer of Medtronic, Inc. on a series of articles on recombinant human Bone Morphogenetic Protein-2 (rhBMP-2) published in a recent edition of *Spine Journal*.
>
> "Integrity and patient safety are my highest priorities. While the *Spine Journal* articles raise questions about researchers' conclusions in their published peer-reviewed literature, the articles do not raise questions about the data Medtronic submitted to the FDA in the approval process or the information available to physicians today through the instructions for use brochure attached to each product sold.
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> "Based on that data, we strongly believe that the safety profile reported to the FDA and summarized in the product label support the safe use of rhBMP-2 for the identified indications. We remain committed to ongoing study of the safety and efficacy of rhBMP-2, especially in applications not covered by FDA labeling.

41. Also on June 28, 2011, Medtronic filed its Form 10-K with the SEC for the period ended April 29, 2011, which included the same results previously reported in its May 24, 2011 press release. The Form 10-K also included a statement about *The Spinal Journal* articles:

> Looking ahead, we expect our Restorative Therapies Group should be impacted by the following:
>
> * * *

- Any effects on our business from discussions in the medical literature, or inquiries from governmental authorities, relating to our INFUSE Bone Graft product. In June 2011, articles in a medical journal suggested that some physicians' peer-reviewed studies may have underreported complications and adverse events associated with INFUSE. These articles did not question the integrity of the data provided by Medtronic to the FDA for product approval or the disclosure of safety issues on the product's Instructions for Use for approved indications.

42. On this news, Medtronic's stock dropped $0.92 per share to close at $38.09 per share on June 29, 2011, a one-day decline of nearly 3% on volume of 10 million shares.

43. Once analysts had a chance to absorb the disclosures in *The Spine Journal*, they downgraded Medtronic's stock, causing further declines in Medtronic's stock price. Analysts stated the following:

- July 5, 2011 – Wells Fargo Securities:

  Summary: We believe the InFuse papers published in The Spine Journal on June 28 will have broader implications for MDT and its spine business than the Street currently expects. We think The Spine Journal papers could lead to the following outcomes: (1) a significant reduction in the sales of MDT's spine biologics franchise; (2) a reduction in the sales of MDT's spinal instrumentation business; (3) a potential FDA review of InFuse, including an Advisory Committee meeting, which could lead to more limited use of InFuse; (4) potentially larger criminal penalties in the Department of Justice (DOJ) investigation of the off-label promotion of InFuse; (5) the potential emergence of class action lawsuits; and (6) the potential sale of the entire spine business. While we previously expected MDT's spine biologics franchise to decline by 9% in FY2012 due to the non-approvable letter for Amplify (higher dose version of InFuse) and a likely DOJ settlement for off-label promotion of InFuse in CY2011, the attack of [sic] InFuse by The Spine Journal and the accompanying negative media coverage was unexpected. Given the increasing negative publicity for InFuse and the likely negative spillover to MDT's larger spinal instrumentation business, we are reducing our FY2012E-13E sales by $209MM and $322MM, respectively, to

> $16.491B and $17.045B. In addition, we are lowering our FY2012E-13E EPS by $0.04 and $0.01, respectively, to $3.43 and $3.74. Our new FY2012E EPS is at the low end of MDT's FY2012 guidance range. We are lowering our valuation range to $36-37 from $46-47 which assumes 10x our new CY2012 EPS estimate.

- July 5, 2011 – J.P. Morgan:

> Surgeons closest to the issue, or at least those that have given it the greatest attention, are having an even stronger reaction. Of the 48 surgeons we surveyed, 63% expect to reduce their Infuse usage in the coming year. But that figure jumps to 90% when we sample those surgeons that have actually read the *TSJ* articles; among this group the decline is 54% – double the overall rate. The [sic] suggests the hit to utilization could increase as physicians take the time to read the details of the articles. An FDA panel to discuss the data, which we view as likely, could also lead to yet another round of negative press for Infuse and further elevate the profile of the concerns raised by the *TSJ* authors.

44. Finally, on August 3, 2011, Medtronic announced it would publicly release Infuse data for Yale researchers to conduct a review. Medtronic agreed to pay Yale $2.5 million to assemble a steering committee, hire two research organizations to review studies of the Infuse product and design a database that could be used by outsiders to get access to the information. Harlan Krumholz, professor of internal medicine, epidemiology and public health at Yale, who was to lead the work, noted: "'It's a historic agreement and one I hope will set a standard for everyone else in the industry. For too long we've been in a situation where questions are raised about the safety of a product but companies don't share the information.'"

45. *Bloomberg News* noted that:

> While it is a good first step, questions will remain after the analysis is done, [Carragee] said. Infuse is predominantly used in surgeries that haven't

> been studied by Medtronic, Carragee said. Thus, the two reviews and the database won't provide any clear answers for those patients, he said.
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> "They simply are not going to have enough data on the main usage of it to give a really precise estimate of how safe or dangerous it is," said Carragee, who is editor in chief of the Spine Journal and led the publication's review of Infuse.
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> The main problem with the published Infuse trial results is that they didn't include the product's complications, Carragee said. Surgeons didn't know to look for things like cancer and male sterility, he said. That will reduce the number of cases reported to the company and U.S. Food and Drug Administration, and they won't show up in the analysis, he said.
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> Diminished Accuracy
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> "The accuracy of that has been severely impacted by 10 years of telling everybody that there are no problems," he said. "I never reported a male sterility event to the company or the FDA because I didn't think it was a complication of the product. It's the same thing for infections or cancer or bladder problems. It was all news to us."

46. On this news, Medtronic's stock dropped $1.47 per share to close at $32.84 per share on August 4, 2011, a one-day decline of nearly 4% on volume of 11.5 million shares.

47. The true facts, which were known by defendants but concealed from the investing public during the Class Period, were as follows:

(a) The Company had engaged in a scheme with certain researchers to downplay the risks and side effects associated with Infuse.

(b) The Company failed to disclose that once the risks associated with the Infuse product were fully appreciated by surgeons, use of the product would drop significantly.

48. The Yale study would ultimately find that there was little to no difference in effectiveness between Infuse and an older method for spurring bone growth, and that there

was substantial evidence of reporting bias in the previous studies on the product. Researchers found Infuse had "'no proven clinical advantage.'"

49. In October 2012, a U.S. Senate Finance Committee report alleged that Medtronic was heavily involved in shaping the content of medical journal articles about Infuse. The report raised questions about research conducted by physicians who received $210 million in royalties and consulting fees over 15 years.

50. As a result of defendants' false statements, Medtronic stock traded at artificially inflated levels during the Class Period. However, after the above revelations seeped into the market, the Company's shares were hammered by massive sales, sending them down nearly 24% from their Class Period high.

LOSS CAUSATION

51. During the Class Period, as detailed herein, defendants made false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Medtronic common stock and operated as a fraud or deceit on Class Period purchasers of Medtronic common stock by misrepresenting the Company's business and prospects. Later, when defendants' prior misrepresentations and fraudulent conduct gradually became apparent to the market, the price of Medtronic common stock fell, as the prior artificial inflation came out of the price over time. As a result of their purchases of Medtronic common stock during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

NO SAFE HARBOR

52. Medtronic's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

53. Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Medtronic who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

CLASS ACTION ALLEGATIONS

54. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Medtronic common stock during the Class Period (the "Class"). Excluded from the Class are defendants and their families, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which defendants have or had a controlling interest.

55. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial

benefits to the parties and the Court. Medtronic has over 1 billion shares of stock outstanding, owned by hundreds if not thousands of persons.

56. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(a) whether the 1934 Act was violated by defendants;

(b) whether defendants omitted and/or misrepresented material facts;

(c) whether defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether defendants knew or deliberately disregarded that their statements were false and misleading;

(e) whether the price of Medtronic common stock was artificially inflated; and

(f) the extent of damage sustained by Class members and the appropriate measure of damages.

57. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

58. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

59. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

60. Plaintiff makes the allegations herein based upon the investigation of plaintiff's counsel, which included a review of regulatory filings made by Medtronic with the SEC, as well as other regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

COUNT I

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

61. Plaintiff incorporates ¶¶1-60 by reference.

62. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

63. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) employed devices, schemes and artifices to defraud;

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Medtronic common stock during the Class Period.

64. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Medtronic common stock. Plaintiff and the Class would not have purchased Medtronic common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

COUNT II

For Violation of §20(a) of the 1934 Act
Against All Defendants

65. Plaintiff incorporates ¶¶1-64 by reference.

66. The Individual Defendants acted as controlling persons of Medtronic within the meaning of §20(a) of the 1934 Act. By virtue of their positions with the Company, and ownership of Medtronic stock, the Individual Defendants had the power and authority to cause Medtronic to engage in the wrongful conduct complained of herein. Medtronic controlled the Individual Defendants and all of its employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

A. Determining that this action is a proper class action, designating plaintiff as Lead Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and plaintiff's counsel as Lead Counsel;

B. Awarding plaintiff and the members of the Class damages, including interest;

C. Awarding plaintiff's reasonable costs and attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

DATED: June 27, 2013

ZIMMERMAN REED, PLLP

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